



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/117,071 10/23/87 WILSON

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EXAMINER

SPENCER AND FRANK
1111 - 19TH STREET NW
WASHINGTON, DC 20036

ARTIST'S PAPER NUMBER

185

DATE MAILED:

02/20/90

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 1-30-90 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-97 are pending in the application.

Of the above, claims 1-74 are withdrawn from consideration.

2. ☒ Claims 1-74 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☐ Claims _____ are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Claims 75-90 and 93-94 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to the host cells used in the instant invention or other mammalian cells. See MPEP 706.03(n) and 706.03(z).

This rejection is maintained with respect to the host cells for essentially the reasons outlined in the last Office. Applicant has responded that "Amplification is a spontaneous event common to most, if not all, cell types." (Specification, p.23). This argument is not persuasive. As noted in the last Office action, the machinery of gene amplification is expected to be cell specific. The claims encompass both lower eucaryotes such as yeast, and plant cells, as well as the mammalian cells exemplified in the disclosure. Applicant has argued that it is unexpected that the GS gene can function as a selectable marker in a cell which is GS plus prior to transformation (amendment, p.16). Applicant has failed to show evidence that amplification of this type has been seen in yeast or plant cells; and, as noted by applicant, nor does the prior art teach such events. The specification is therefore considered not commensurate in scope with the claims.

Claims 75-95 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 75 et seq are vague and indefinite in the recitation of the phrase "capable of expressing both a recombinant ..."; capable of does not explicitly express what it does. This rejection could be obviated by the use of "an expression vector comprising 2 expression units, one for the GS gene and

one for the gene of the desired protein". In the same manner, claims 83 et seq could be amended to recite "two expression vectors, one comprising..". The same rejection is made to claims 93, 94, and 95; and the same amendment to the wording is suggested.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

Claims 95-97 are rejected under 35 U.S.C. 103 as being unpatentable over Sanders et al in view of Pennica et al.

This rejection is maintained for essentially the reasons outlined in the last Office action. Applicant has responded that Sanders teaches the cloning of the partial GS gene and Pennica et al relates solely to the production of tPA by recombinant means. This argument is not persuasive. Pennica et al also teaches methods of obtaining a complete cDNA clone when in possession of a partial clone (Pennica et al, p.216). It is maintained that it would have been obvious to use the method of Pennica et al to isolate a full length version of the clone of Sanders et al. In addition, the expression of a second polypeptide is known because cloning vectors contain second genes which

are expressed such as selectable markers. Further, as is noted in applicant's response (p.21-22), the use of various known promoters and vectors is well known in the art. Thus, different vectors in which the gene has been subcloned are considered obvious over the prior art of the vectors and the gene itself.

Claims 75- 94 are considered free of the prior art.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY

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PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF
THIS FINAL ACTION.

An inquiry concerning this communication should be directed to
Sherry Nolan at telephone number (703) 557-0938.

S. Nolan

Robin Teskin
ROBIN TESKIN
EXAMINER
ART UNIT 185